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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin and Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved single-ingredient monensin and roxarsone Type A medicated articles to make two-way combination drug Type C medicated feed used as an aid in the prevention of coccidiosis and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-139 that provides for use of Coban® (45 or 60 grams per pound (g/lb) of monensin as monensin sodium) and 3-Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination Type C medicated feeds for replacement chickens intended for use as caged layers. The Type C medicated feeds contain 90 to 110 g/ton monensin and 22.7 to 45.4 g/ton roxarsone, and they are used as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA

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is approved as of June 28, 2000, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraph (f)(4)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(4) * * *

(iv) *Amount per ton.* Monensin, 90 to 110 grams, plus roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdose

or lack of water may result in leg weakness or paralysis. As monensin sodium provided by 000986; roxarsone as provided by 046573 in § 510.600(c) of this chapter.

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Dated: 7/25/00
July 25, 2000

Stephen F. Sundlof
Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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M. A. Bryant